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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	93004	2429

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,518	JAROSZESKI ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,8,10,21,22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,8,10,21,22 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 8/16/2006.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are currently pending and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,678,558 B1 (Dimmer et al.).

Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the

application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell (claims 1, 21, 24); wherein the duration of the applying step is in the range of 200ms to 100 sec (claims 2 and 22); wherein the electric field comprises a square, bipolar, or sinusoidal pulse waveform (claims 6, 25) and wherein the electric field comprises a pulse comprising a combination of at least two of the indicated pulse waveforms (claim 26); wherein the injection step is by syringe injection (claims 8, 27); wherein the target tissue is skin or tumor tissue (claims 10, 28).

Specifically, Dimmer et al. teaches a method for delivering an agent such as a nucleic acid into a cell of a target tissue (such as skin or tumor tissue) using an electric signal that has a bipolar waveform (e.g., see abstract), wherein the agent is injected directly by needle and syringe (e.g., see column2 lines 24-27), wherein the electric signal can have a bipolar, square or sinusoidal waveform (e.g., see column 5, lines 35-36; column 8, lines 17-30), wherein the electric signal can be a plurality of electric signals (e.g., see column 9, lines 10-16) wherein the electric field(s) are in the range of 1mV/cm to 200V/cm (e.g., 25V/cm or 100V/cm see column 10, lines 29-42); wherein the electric field is applied for a duration of 200ms-20minutes (e.g., most preferably about 50μs-400ms see column 10, lines 54-60). (Also see column 13, lines 7-7-19; column 14, lines 21-23; column 23, lines 1-11; column 24, lines 43-50; column 29, lines 12-15; claims 1, 10, 11, 16, 17, 25).

Therefore, Dimmer et al. anticipates the instant claims.

Response to Arguments

Applicant's arguments filed 8/16/2006 have been fully considered but they are not persuasive.

Applicants argue that the "total electroporation signal duration" is the sum of the first polarity durations and the second polarity durations of each electroporation signal included in a single electroporation therapy treatment. Applicants assert that the "total electroporation signal duration of between 200ms and 20 minutes" as described by Dimmer consists of at least one bipolar pulse having a first polarity and a second polarity. Based on this analysis, Applicants conclude that the "total electroporation signal duration" as described by Dimmer is not equivalent to the "continuous electric field applied for a duration of 200ms to 20 minutes" as disclosed and claimed by the present invention because the total electroporation signal duration of Dimmer includes at least one bipolar pulse having at least two different polarity signals which would not be considered a continuous electric field as claimed by the present invention.

In response, contrary to Applicants assertion, Dimmer does not require that the total electroporation signal duration must include at least one bipolar pulse having at least two different polarity signals. For instance, at column 20, lines 41-44, Dimmer explicitly teaches, "The total electroporation signal duration is preferably less than about 10 seconds, more preferably about 30μs-10 seconds, even more preferably about 30μs -1 ms and most preferably about 50μs -400 ms". Furthermore, Dimmer teaches that the electroporation signal is not only limited to a bipolar signal, but may also be a monopolar signal. Specifically, Dimmer teaches:

> "Although the preferred electroporation signal has a bipolar square waveform, the present invention is not limited to these waveforms. For instance, suitable electroporation signal waveforms include, but are not limited to, monopolar, triangular, circular, sinusoidal and exponential waveforms." (See column 8, lines 22-27).

Therefore, taken as a whole, Dimmer teaches administering an electroporation signal for a total electroporation signal in the claimed range of 200ms to 20 minutes, wherein the electroporation signal can be a monopolar signal. Therefore Dimmer teaches administration of a monopolar signal for a total signal duration of preferably less than about 10 seconds, more preferably about 30μs-10 seconds... and most preferably about 50μs -400 ms, which thus anticipates the instant claims.

Furthermore, it is also respectfully pointed out that the instant application explicitly claims applying an electric field consisting of a single continuous electric field wherein the electric field comprises a bipolar pulse (see claims 6 and 25). Therefore, applying a single bipolar pulse as taught by Dimmer, and which would include a first and second polarity, must be encompassed by the broad claims.

Applicants also argue that Dimmer states that the therapeutic electrical signals preferably have a pulse duration of less than about 50μs.

It is respectfully pointed out that although a pulse length of less than about 50μs may be preferable, Dimmer also explicitly teaches, "The total electroporation signal duration is most preferably about 50μs -400 ms" (see column 20, lines 41-44). Furthermore, Dimmer teaches that the electroporation signal is not only limited to a bipolar signal, but may also be a monopolar signal. Therefore, Dimmer teaches several different types of signals, including application of a monopolar signal wherein the total signal duration of the monopolar signal would be "most preferably about 50μs -400 ms".

Applicants also argue that the agent movement signal taught by Dimmer is not used for electroporation, but instead for the movement of the agent towards the cell. Applicants contend that the agent movement signal as described by Dimmer does not effect a change in porosity of the cell. As such, Applicants assert that the agent movement signal therefore does not anticipate the instant claims because Dimmer only teaches that the agent movement signal moves that agent towards the cells and does not teach that the agent movement signal effects a change in porosity of the cell. However, as acknowledged by Applicants, at col. 14, lines 21-23, Dimmer describes an agent movement signal having a potential of about 5V-200V and more preferably about 10V-100V, having a duration of the agent movement signal of preferably about 100μs-10 seconds. Therefore, Dimmer teaches administration of an electric signal that meets the voltage and duration limitations of the claims. As such, the administration of the "agent movement signal" as described by Dimmer, would necessarily have the same result as the claimed method. In other words, since the agent movement signal taught by Dimmer meets the voltage and duration limitations of the claims it must have the same effect on the cells. Thus, application of the agent movement signal, as described by Dimmer would necessarily result in a change in the porosity of the cell sufficient to facilitate entry of the desired molecule into the cell.

Applicant is reminded that MPEP 2112.01 teaches, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Therefore, Applicants arguments are not persuasive.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON E. ANGELL, PH.D.
PRIMARY EXAMINER